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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,297	03/23/2001	Jacqueline A. Oldham	39-236	4610

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EXAMINER
EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,297	OLDHAM, JACQUELINE A.	
	Examiner	Art Unit	
	George R Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/202289

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, "comprising..." is vague since the limitations are additional limitations. It is suggested to use "further comprising". In line 3, "an electrode connector" is vague since it is unclear if this is for the means for applying the signal or an electrode (which has not been claimed). It is suggested to state "an electrode connector connected to said means for applying". In line 4, "electrode connection" should be "electrode connector".

In claim 12, "comprising" is vague since the limitation is an additional limitation. It is suggested to use "further comprising".

In claim 13, "the handheld unit comprising" is vague. It is suggested to use "wherein the hand held unit further comprises a programmable...". In line 2, "which can be controlled" is vague since it is unclear if the limitation after the means is being claimed. It is suggested to use "adapter to be". In addition, "programmable means" is vague since the function of the means is unclear ("programming means").

In claim 14, "the hand held unit comprising" is vague. In addition, the claim is incomplete for omitting essential structural cooperative relationship between elements

amounting to a gap in the structure since the means for storing is not connected to any other element. The claim is just a listing of parts.

In claim 15, "comprising" is vague. It is suggested to use "further compri ;ing". In line 2, "said" should be inserted before "patient".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cywinski (5350415). For claims 4-7, for the doublet, Cywinski states in column ›, line 20 that the high rate has an interpulse interval of about 10-20 ms and in line 27 that the pulses last for about 40 ms. Using the about 20 ms pulse interval and about 40 ms pulse train will provide the claimed doublet.

Claims 1-7 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Campos (5097833).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cywinski. Cywinski discloses the claimed invention but does not disclose expressly the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms (claim 8) or the pulses at the various pulse intervals (claims 9 and 10). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the trophic stimulation of muscles as taught by Cywinski with the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms or the pulses at the various pulse intervals, because Applicant has not disclosed that the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms or the pulses at the various pulse intervals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with trophic stimulation of muscles as taught by Cywinski, because his stimulation pattern mimics the motor unit action potentials that are naturally generated when muscles are innervated and provides for trophic stimulation of muscles.

Therefore, it would have been an obvious matter of design choice to modify Cywinski to obtain the invention as specified in the claim(s).

Claims 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campos. Campos discloses the claimed invention but does not disclose expressly the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms (claim 8) or the pulses at the various pulse intervals (claims 9 and 10) or the user amplitude adjustment means (claim 12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the muscle stimulator as taught by Campos, with an user amplitude adjustment means since it was known in the art that muscle stimulators have means for adjusting the amplitude of the stimulation to allow the user to select a comfortable level for the stimulation.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the muscle stimulator as taught by Campos with the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms or the pulses at the various pulse intervals, because Applicant has not disclosed that the pulses consisting of pulses at 500 ms, 20 ms, and 12 ms or the pulses at the various pulse intervals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with multiple frequency stimulation pattern as taught by Campos, because his stimulation pattern provides a high therapeutic effect for muscles with minimal resulting discomfort.

Therefore, it would have been an obvious matter of design choice to modify Campos to obtain the invention as specified in the claim(s).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12, and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6236890. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spacing of the pulses as taught by Oldham, with the spacing of the pulses at 500, 20 and 12 milliseconds and with pulse trains consisting of pulse times at various intervals since it was known in the art that pulses trains timed at these various intervals provide an effective treatment to muscles.

Allowable Subject Matter

Claims 11 and 13-15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762
11/12/2

GRE
November 18, 2002